

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	1	of	10	Attorney Docket Number	224491


U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Filing Date if appropriate MM-DD-YYYY
		Document Number	Kind Code			
JER	IY	US- 5,003,097		03-26-1991	Beaucage et al.	
JER	IZ	US- 5,264,423		11-23-1993	Cohen et al.	
JER	JA	US- 5,276,019		01-04-1994	Cohen et al.	
JER	JB	US- 5,286,717		02-15-1994	Cohen et al.	
JER	JC	US- 5,965,519		10-12-1999	Yatvin et al.	
JER	JD	US- 6,126,965		10-03-2000	Kasid et al.	
JER	JE	US- 6,183,958		02-06-2001	Stanton, Jr.	
JER	JF	US- 6,291,175		09-18-2001	Sévigny et al.	
JER	JG	US- 6,333,314		12-25-2001	Kasid et al.	
JER	JH	US- 6,368,797		04-09-2002	Schappert	
JER	JI	US- 6,395,481		05-28-2002	Di Rienzo et al.	
JER	JJ	US- 6,475,736		11-05-2002	Stanton, Jr. et al.	
JER	JK	US- 6,559,129		05-06-2003	Kasid et al.	
JER	JL	US- 6,500,650		12-31-2002	Stanton, Jr. et al.	
JER	JM	US- 6,537,759		03-25-2003	Stanton, Jr. et al.	
JER	JN	US- 6,573,049		06-03-2003	Schappert	
JER	JO	US- 6,582,923		06-24-2003	Stanton, Jr. et al.	
JER	JP	US- 6,610,492		08-26-2003	Stanton, Jr. et al.	
JER	JQ	US- 6,664,062		12-16-2003	Stanton, Jr.	
JER	JR	US- 2002/0150943	A1	10-17-2002	Stanton, Jr. et al.	
JER	JS	US- 2003/0073123	A1	04-17-2003	Shen et al.	
JER	JT	US- 2003/0215489	A1	11-20-2003	Kasid et al.	
JER	JU	US- 2003/0219476	A1	11-27-2003	Ahmad et al.	
JER	JV	US- 2003/0225023	A1	12-04-2003	Kasid et al.	
JER	JW	US- 2003/0228317	A1	12-11-2003	Gokhale et al.	

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
-----------------------	------------------	--------------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2008. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/717,378
				Filing Date	November 19, 2003
				First Named Inventor	RAHMAN, Aquilur
				Group Art Unit	1654
				Examiner Name	RUSSEL, Jeffrey E.
Sheet	2	of	10	Attorney Docket Number	224491


U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Filing Date, if appropriate MM-DD-YYYY
		Document Number	Kind Code			
JER	JX	US- 2003/0229040	A1	12-11-2003	Kasid et al.	
JER	JY	US- 2004/0005603	A1	01-08-2004	Kasid et al.	
JER	JZ	US- 2004/0082771	A1	04-29-2004	Kasid et al.	
JER	KA	US- 2004/0106571	A1	06-03-2004	Kasid et al.	
JER	KB	US- 2004/0115714	A1	06-17-2004	Kasid et al.	
JER	KC	US- 2004/0248218	A1	12-09-2004	Kasid et al.	
JER	KD	US- 2005/0002918	A1	01-06-2005	Strauss et al.	
JER	KE	US- 2005/0019387	A1	01-27-2005	Rahman et al.	
JER	KF	US- 2005/0148528	A1	07-07-2005	Gately	
JER	KG	US- 2005/0153297	A1	07-14-2005	Ahmad et al.	
JER	KH	US- 2005/0181037	A1	08-18-2005	Ahmad et al.	
JER	KI	US- 2005/0202074	A1	09-15-2005	Rahman	
JER	KJ	US- 2005/0238706	A1	10-27-2005	Ahmad et al.	
JER	KK	US- 2005/0249795	A1	11-10-2005	Zhang et al.	
JER	KL	US- 2005/0266068	A1	12-01-2005	Ahmad et al.	
JER	KM	US- 2005/0277611	A1	12-15-2005	Ahmad et al.	
JER	KN	US- 09/354,109			Kasid et al.	07-15-1999
JER	KO	US- 09/930,283			Kasid et al.	08-16-2001
JER	KP	US- 10/056,210			Kasid et al.	01-28-2002
JER	KQ	US- 10/239,598			Rahman	10-25-2000
JER	KR	US- 10/680,313			Kasid et al.	10-06-2003
JER	KS	US- 60/041,192			Kasid et al.	03-21-1997
JER	KT	US- 60/241,069			Rahman et al.	10-16-2000
JER	KU	US- 60/264,062			Kumar et al.	01-26-2001
JER	KV	US- 60/281,779			Kasid et al.	04-06-2001

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
--------------------	------------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	3	of	10	Attorney Docket Number	224491


U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Filing Date, if appropriate MM-DD-YYYY
		Document Number	Kind Code			
JER	KW	US- 60/281,780			Kasid et al.	04-06-2001
JER	KX	US- 60/281,785			Kasid	04-06-2001
JER	KY	US- 60/281,796			Kasid et al.	04-06-2001
JER	KZ	US- 60/314,959			Rahman et al.	08-24-2001
JER	LA	US- 60/332,477			Strauss et al.	11-09-2001
JER	LB	US- 60/371,116			Kasid et al.	04-10-2002
JER	LC	US- 60/371,126			Kasid et al.	04-10-2002
JER	LD	US- 60/382,031			Gokhale et al.	05-22-2002
JER	LE	US- 60/382,411			Gately	05-20-2002
JER	LF	US- 60/383,340			Ahmad et al.	05-24-2002
JER	LG	US- 60/384,222			Ahmad et al.	05-29-2002
JER	LH	US- 60/405,378			Zhang et al.	08-23-2002
JER	LI	US- 60/419,277			Ahmad et al.	10-16-2002
JER	LJ	US- 60/429,285			Ahmad et al.	11-26-2002
JER	LK	US- 60/438,659			Ahmad et al.	01-07-2003
JER	LL	US- 60/444,958			Zhang et al.	02-03-2003
JER	LM	US- 60/446,895			Bhamidipati et al.	02-11-2003
JER	LN	US- 60/457,898			Gately et al.	03-26-2003
JER	LO	US- 60/467,331			Ahmad et al.	05-02-2003
JER	LP	US- 60/472,664			Jamil et al.	05-22-2003
JER	LQ	US- 60/480,669			Jamil et al.	06-23-2003
JER	LR	US- 60/495,260			Jamil et al.	08-13-2003
JER	LS	US- 60/514,658			Ahmad et al.	10-27-2003

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
-----------------------	------------------	--------------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/717,378
				Filing Date	November 19, 2003
				First Named Inventor	RAHMAN, Aquilur
				Group Art Unit	1654
Examiner Name	RUSSEL, Jeffrey E.				
Sheet	4	of	10	Attorney Docket Number	224491


FOREIGN PATENT DOCUMENTS								
Examiner Initials¹	Cite No.	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	Check if Translation Provided²
		Office	Number	Kind Code				
JER	LT	EP	0 288 255	A2	10-26-1988	The Japanese Research and Development Association for Bioreactor System		<input type="checkbox"/>
JER	LU	EP	1 352 970	A1	10-15-2003	Nagoya Industrial Science Research Institute		<input type="checkbox"/>
JER	LV	SU	629927	A	10-30-1978	Bacterial Preparation Works		<input checked="" type="checkbox"/>
JER	LW	SU	1186212	A	10-23-1985	Inst. Biologicheskoy Med. Khimii		<input checked="" type="checkbox"/>
JER	LY	WO	98/43095	A	10-01-1998	Georgetown Univ.		<input type="checkbox"/>
JER	LY	WO	00/01366	A	01-13-2000	NeoPharm, Inc.		<input type="checkbox"/>
JER	MZ	WO	00/52210	A	09-08-2000	Variagenics, Inc.		<input type="checkbox"/>
JER	MA	WO	01/53460	A	07-26-2001	Variagenics, Inc.		<input type="checkbox"/>
JER	MB	WO	01/70220	A	09-27-2001	NeoPharm, Inc.		<input type="checkbox"/>
JER	MC	WO	02/32400	A	04-25-2002	NeoPharm, Inc.		<input type="checkbox"/>
JER	MD	WO	02/059337	A	08-01-2002	Georgetown Univ. School of Medicine		<input type="checkbox"/>
JER	ME	WO	02/081639	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
JER	MF	WO	02/081640	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
JER	MG	WO	02/081641	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
JER	MH	WO	02/081642	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
JER	MI	WO	02/088714	A	11-07-2002	McGill University		<input type="checkbox"/>
JER	MJ	WO	03/013536	A	02-20-2003	Epidaurus Biotechnologie AG		<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
-----------------------	------------------	--------------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2008. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/717,378
				Filing Date	November 19, 2003
				First Named Inventor	RAHMAN, Aquilur
				Group Art Unit	1654
				Examiner Name	RUSSEL, Jeffrey E.
Sheet	5	of	10	Attorney Docket Number	224491

FOREIGN PATENT DOCUMENTS								
Examiner Initials ¹	Cite No.	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	Check if Translation Provided**
		Office	Number	Kind Code				
JER	MK	WO	03/013537	A	02-20-2003	Epidauros Biotechnologie AG		<input type="checkbox"/>
JER	ML	WO	03/018018	A	03-06-2003	NeoPharm, Inc.		<input type="checkbox"/>
JER	MM	WO	03/039600	A	05-15-2003	NeoPharm, Inc.		<input type="checkbox"/>
JER	MN	WO	03/070221	A	08-28-2003	Georgetown Univ.		<input type="checkbox"/>
JER	MO	WO	03/099213	A	12-04-2003	NeoPharm, Inc.		<input type="checkbox"/>
JER	MP	WO	03/099830	A	12-04-2003	NeoPharm, Inc.		<input type="checkbox"/>
JER	MQ	WO	03/102011	A	12-11-2003	NeoPharm, Inc.		<input type="checkbox"/>
JER	MR	WO	2004/017944	A	03-04-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MS	WO	2004/035523	A	04-29-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MT	WO	2004/039817	A	05-13-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MU	WO	2004/062569	A	07-29-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MV	WO	2004/069224	A	08-19-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MW	WO	2004/071466	A	08-26-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MX	WO	2004/087758	A	10-14-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MY	WO	2005/000266	A	01-06-2005	NeoPharm, Inc.		<input type="checkbox"/>
JER	MZ	WO	2005/000318	A	01-06-2005	NeoPharm, Inc.		<input type="checkbox"/>
JER	NA	WO	2005/042028	A	05-12-2005	NeoPharm, Inc.		<input type="checkbox"/>
JER	NB	WO	2005/067632	A	07-28-2005	NeoPharm, Inc.		<input type="checkbox"/>


OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
JER	NC	Office Action mailed December 30, 2005, in U.S. Patent Application No. 10/424,258.	<input type="checkbox"/>
JER	ND	ANDO et al., "UGT1A1 genotypes and glucuronidation of SN-38, the active metabolite of irinotecan," <i>Ann. Oncol.</i> , 9, 845-847 (1998).	<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
--------------------	------------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2008. OMB 0851-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
Examiner Name	RUSSEL, Jeffrey E.				
Sheet	6	of	10	Attorney Docket Number	224491


OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
JER	NE	ANDO et al., "Polymorphisms of UDP-glucuronosyltransferase gene and irinotecan toxicity: a pharmacogenetic analysis," <i>Cancer Res.</i> 60, 6921-6926 (2000).	<input type="checkbox"/>
JER	NF	BOSMA et al., "Bilirubin UDP-glucuronosyltransferase 1 is the only relevant bilirubin glucuronidating isoform in man," <i>J. Biol. Chem.</i> 269, 17960-17964 (1994).	<input type="checkbox"/>
JER	NG	BOSMA et al., "The genetic basis of the reduced expression of bilirubin UDP-glucuronosyltransferase 1 in Gilbert's syndrome," <i>New Engl. J. Med.</i> 333, 1171-1175 (1995).	<input type="checkbox"/>
JER	NH	CERSOSIMO et al., "A new antineoplastic agent for the management of colorectal cancer," <i>Ann. Pharmacother.</i> 32:1324-1333, (1998)	<input type="checkbox"/>
JER	NI	DRUMMOND et al., "Optimizing Liposomes for Delivery of Chemotherapeutic Agents to Solid Tumors," <i>Pharmacol. Rev.</i> 51, 691-743 (1999).	<input type="checkbox"/>
JER	NJ	FISHMAN et al., "Phase I study of Liposomal SN-38 (LE-SN38) in Patients With Advanced Cancer: Pharmacogenomics and Pharmacokinetics," <i>AARC-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics</i> (Boston, MA), Abstract B250 (November 2003).	<input type="checkbox"/>
JER	NK	FISHMAN et al., "Phase I study of liposome encapsulated mitoxantrone (LEM) in patients with advanced cancers," <i>Ann. Oncol.</i> 13 (Suppl. 5), 23 (2002).	<input type="checkbox"/>
JER	NL	GILBERT et al., "Phase I study of 9-nitrocamptothecin (9-NC) liposome aerosol for the treatment of primary and metastatic cancer to the lungs: effect of dose escalation on bronchoalveolar lavage (BAL) and plasma drug levels," <i>Proc. Am. Assoc. Cancer Res.</i> , 43, 430 (Abstract 2138) (2002).	<input type="checkbox"/>
JER	NM	GUPTA et al., "Metabolic fate of irinotecan in humans: correlation of glucuronidation with diarrhea," <i>Cancer Res.</i> 54, 3723-3725 (1994).	<input type="checkbox"/>
JER	NN	GUTBERLET et al., "Cardiolipin, α -D-glucopyranosyl, and L-lysylcardiolipin from Gram-positive bacteria: FAB MS, monifilm and X-ray powder diffraction studies," <i>Biochim. Biophys. Acta</i> , 463, 307-322 (2000).	<input type="checkbox"/>
JER	NO	HECHT, "Gastrointestinal toxicity of irinotecan," <i>Oncology</i> 12, 72-78 (1998).	<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
--------------------	------------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2008. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	7	of	10	Attorney Docket Number	224491


OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**	
JER	NP	HSIANG et al., "Arrest of replication forks by drug-stabilized topoisomerase I-DNA cleavable complexes as a mechanism of cell killing by camptothecin," <i>Cancer Res.</i> 49, 5077-5082 (1989).	<input type="checkbox"/>	
JER	NQ	HSIANG et al., "Camptothecin induces protein-linked DNA breaks via mammalian DNA topoisomerase I," <i>J. Biol. Chem.</i> 260, 14873-14878 (1985).	<input type="checkbox"/>	
JER	NR	INNOCENTI et al., "UGT1A1 *28 polymorphism is a predictor of neutropenia in irinotecan chemotherapy," <i>Proc. Am. Soc. Clin. Oncol.</i> , 22, 124 (Abstract 495) (2003).	<input type="checkbox"/>	
JER	NS	IYER et al., "Genetic predisposition to the metabolism of irinotecan (CPT-11). Role of uridine diphosphate glucuronosyltransferase isoform 1A1 in the glucuronidation of its active metabolite (SN-38) in human liver microsomes," <i>J Clin Invest</i> 101:847-854, (1998)	<input type="checkbox"/>	
JER	NT	IYER et al. "Phenotype-genotype correlation of in vitro SN-38 (active metabolite of irinotecan) and bilirubin glucuronidation in human liver tissue with UGT1 A1 promoter polymorphism," <i>Clin. Pharmacol. Ther.</i> , 65, 576-582 (1999).	<input type="checkbox"/>	
JER	NU	IYER et al., "UGT1A1 *28 polymorphism as a determinant of irinotecan disposition and toxicity," <i>Pharmacogenetics</i> , 2, 43-47 (2002).	<input type="checkbox"/>	
JER	NV	KEHRER et al., "Factors involved in prolongation of the terminal disposition phase of SN-38: clinical and experimental studies," <i>Clin. Cancer Res.</i> , 6, 3451-3458 (2000).	<input type="checkbox"/>	
JER	NW	KNIGHT et al., "Anticancer effect of 9-nitrocamptothecin liposome aerosol on human cancer xenografts in nude mice," <i>Cancer Chemother. Pharmacol.</i> , 44, 177-186 (1999).	<input type="checkbox"/>	
JER	NX	KRAUT et al., "Pharmacogenomic and pharmacokinetic assessment of liposome encapsulated SN-38 (LE-SN38) in advanced cancer patients," presented at ASCO (American Society of Clinical Oncology), New Orleans, LA, June 5-8, 2004, Abstract 2501 (June 5, 2004).	<input type="checkbox"/>	

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
--------------------	------------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2008. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	8	of	10	Attorney Docket Number	224491


OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided ²	
JER	NY	KUNIMOTO et al., "Antitumor activity of 7-ethyl-10-[4-(1-piperidino)-1-piperidino]carbonyloxy-camptothecin, a novel water soluble derivative of camptothecin, against murine tumors," <i>Cancer Res.</i> 47:5944-5947, (1987)	<input type="checkbox"/>	
JER	NZ	LAMPE et al., "UDP-glucuronosyltransferase (UGT1A1 *28 and UGT1A6*2) polymorphisms in Caucasians and Asians: relationships to serum bilirubin concentrations," <i>Pharmacogenetics</i> , 9, 341-349 (1999).	<input type="checkbox"/>	
JER	OA	LAVELLE et al. "Preclinical evaluation of CPT-1 1 and its active metabolite SN-38," <i>Semin. Oncol.</i> , 23, 11-20 (1996).	<input type="checkbox"/>	
JER	OB	MATHIJSSEN et al., "Impact of body-size measures on irinotecan clearance: alternative dosing recommendations," <i>J. Clin. Oncol.</i> , 20, 81-87 (2002).	<input type="checkbox"/>	
JER	OC	MONAGHAN et al., "Genetic variation in bilirubin UDP-glucuronosyltransferase gene promoter and Gilbert's syndrome," <i>Lancet</i> , 347, 578-581 (1996).	<input type="checkbox"/>	
JER	OD	O'LEARY et al, "Camptothecins: a review of their development and schedules of administration," <i>Eur. J. Cancer.</i> , 34, 1500-1508 (1998).	<input type="checkbox"/>	
JER	OE	OSBORNE, "Nastech licenses RNAi patents to boost tight junctions work," <i>BioWorld Today</i> , 15 (21), 1, 6 (February 3, 2004).	<input type="checkbox"/>	
JER	OF	PFIZER, INC., Package insert for Camptosar® (July 2005).	<input type="checkbox"/>	
JER	OG	PITOT et al, "Phase I dose-finding and pharmacokinetic trial of irinotecan hydrochloride (CPT-11) using a once-every-three-week dosing schedule for patients with advanced solid tumor malignancy," <i>Clin Cancer Res.</i> , 6, 2236-2244 (2000).	<input type="checkbox"/>	
JER	OH	RAINIER et al., "Phase transition characteristics of diphosphatidyl-glycerol (cardiolipin) and stereoisomeric phosphatidylglycerol bilayers: mono- and divalent metal ion effects," <i>Biochim. Biophys. Acta</i> , 558, 187-198 (1979).	<input type="checkbox"/>	
JER	OI	RIVORY et al, "Kinetics of the in vivo interconversion of the carboxylate and lactone forms of irinotecan (CPT-11) and of its metabolite SN-38 in patients," <i>Cancer Res.</i> 54:6330-6333, (1994)	<input type="checkbox"/>	

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
--------------------	------------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2008. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	9	of	10	Attorney Docket Number	224491

OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**	
JER	OJ	RIVORY et al, "Pharmacokinetic interrelationships of irinotecan (CPT-11) and its three major plasma metabolites in patients enrolled in phase I/II trials," <i>Clin. Cancer Res.</i> , 3, 1261-1266 (1997).	<input type="checkbox"/>	
JER	OK	RIVORY, "Metabolism of CPT-11 impact on activity," <i>Ann. N. Y. Acad. Sci.</i> , 922, 205-215 (2000).	<input type="checkbox"/>	
JER	OL	ROTHENBERG, "Topoisomerase I inhibitors: review and update," <i>Ann. Oncol.</i> 8:837-855, (1997)		
JER	OM	SANGHANI et al., "Carboxylesterases expressed in human colon tumor tissue and their role in CPT-11 hydrolysis," <i>Clin. Cancer Res.</i> , 9 (13), 4983-4991 (October 15, 2003).	<input type="checkbox"/>	
JER	ON	SASAKI et al., "Pharmacological correlation between total drug concentration and lactones of CPT-11 and SN-38 in patients treated with CPT-11," <i>Cancer Res.</i> , 86, 111-116 (1995).	<input type="checkbox"/>	
JER	OO	SCHAEPPi et al., "Toxicity of camptothecin (NSC-100880)," <i>Cancer Chemother. Rep.</i> , 5, 25-36 (1974).	<input type="checkbox"/>	
JER	OP	SLATTER et al., "Pharmacokinetics, metabolism and excretion of irinotecan (CPT-11) following iv infusion of [14C]CPT-11 in cancer patients," <i>Drug Metab. Dispos.</i> , 28, 423-433 (2000).	<input type="checkbox"/>	
JER	OQ	STRASSBURG et al., "Jaundice, genes and promoters," <i>J. Hepatol.</i> , 33, 467-479 (2000).	<input type="checkbox"/>	
JER	OR	TAKIMOTO et al., "The camptothecins," in <i>The camptothecins. Cancer chemotherapy and biotherapy</i> , 2nd ed. (Chabner et al., eds.), Chapter 19, 463-484 (Lippincott-Raven, Philadelphia, PA, 1996).	<input type="checkbox"/>	
JER	OS	TREAT et al., "Phase I trial in advanced malignancies with liposome encapsulated paclitaxel (LEP)," <i>Clin. Cancer Res.</i> , 6, 4492s (2000).	<input type="checkbox"/>	
JER	OT	VANHOEFER et al., "Irinotecan in the treatment of colorectal cancer: clinical overview," <i>J. Clin. Oncol.</i> , 19, 1501-1518 (2001).	<input type="checkbox"/>	

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
--------------------	------------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → +

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2008. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/717,378
				Filing Date	November 19, 2003
				First Named Inventor	RAHMAN, Aquilur
				Group Art Unit	1654
				Examiner Name	RUSSEL, Jeffrey E.
Sheet	10	of	10	Attorney Docket Number	224491

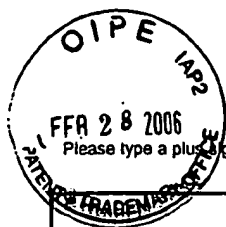
OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
JER	OU	VAUGHN et al., "A phase I study of a new liposome encapsulated doxorubicin (LED) formulation in advanced malignancies," <i>Proc. Am. Soc. Clin. Oncol.</i> , 19 (23), 1a (Abstract 892) (1999).	<input type="checkbox"/>
JER	OV	WADLER et al., "Recommended guidelines for the treatment of chemotherapy-induced diarrhea," <i>J. Clin. Oncol.</i> , 16, 3169-3178 (1998).	<input type="checkbox"/>
JER	OW	WASSERMAN et al., "Severe CPT-11 toxicity in patients with Gilbert's syndrome: two case reports," <i>Ann. Oncol.</i> , 8, 1049-1051 (1997).	<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
--------------------	------------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/717,378
				Filing Date	November 19, 2003
				First Named Inventor	RAHMAN, Aquilur
				Group Art Unit	1654
				Examiner Name	RUSSEL, Jeffrey E.
Sheet	1	of	1	Attorney Docket Number	224491

U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Filing Date if appropriate MM-DD-YYYY
		Document Number	Kind Code			

FOREIGN PATENT DOCUMENTS								
Examiner Initials ¹	Cite No.	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	Check If Translation Provided**
		Office	Number	Kind Code				
JER	OX	WO	00/50639	A	08-31-2000	Variagenics, Inc.		<input type="checkbox"/>
								<input type="checkbox"/>
								<input checked="" type="checkbox"/>
								<input type="checkbox"/>

OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

/Jeffrey Russel/

05/02/2006